Spacelabs medical

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Certified Mail/Return Receipt Requested
Ms. Magalie Roman Salas
Office of Secretary
Federal Communications Commission
The Portals
445 12th Street SW
Room TW-A325
Washington, DC 20554

re: Notice of Proposed Rulemaking Released July 16, 1999
ET Docket 99-255

Dear Ms. Salas:

Spacelabs Medical, Inc. is pleased to provide the Federal Communications Commission with an original and four copies of the attached comments concerning the Notice of Proposed Rulemaking (NPRM), ET Docket 99-255, establishing the Wireless Medical Telemetry Services (WMTS).

Sincerely,

Eugene V. DeFelice

Eugene V. DeFelice
Vice President, General Counsel
and Secretary

Enclosure

Diskette copies sent to: Hugh L. Van Tuyl, Office of Engineering & Technology
and to: International Transcription Service, Inc.

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Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Amendment of Parts 2 and 95 of	)	
the Commission's Rules to Create a	)	ET Docket No. 99-255
Wireless Medical Telemetry Service	)	
	)	

To: The Commission

COMMENTS OF
SPACELABS MEDICAL, INC.

Spacelabs Medical, Inc. (Spacelabs) hereby responds to the Notice of Proposed Rulemaking (NPRM), issued by the Commission in the above-captioned proceeding proposing to establish the Wireless Medical Telemetry Service (WMTS).

I. INTRODUCTION

Spacelabs is a publicly traded company engaged in the manufacturing and marketing of patient monitoring systems and clinical information systems. Spacelabs has long been an industry leader in biomedical telemetry monitoring. As a contractor for the manned space flight program, Spacelabs collaborated with NASA in developing systems to monitor the vital signs of astronauts in space. For more than forty years, Spacelabs has steadily advanced the art of high-performance telemetry monitoring for healthcare. Most recently, Spacelabs has participated as a member of the American Hospital Association's Task Force on Medical Telemetry.

Medical telemetry has become a cornerstone of today's health care environment. It is used in the vast majority of hospitals throughout the United States and is an essential component in improving patient recovery and reducing costs. It is from this perspective that Spacelabs welcomes the action of the FCC in moving toward at least partially addressing important issues vital to medical telemetry users and their patients. Spacelabs firmly believes that it is a critical public policy mandate of the FCC to ensure the protection of medical telemetry, to ensure that telemetry is allowed to operate on sufficient dedicated interference-free spectrum, and to ensure an adequate transition plan is developed and implemented so as to avoid disruption of this crucial medical service.

II. DISCUSSION

1. ***Spacelabs Medical strongly supports the Commission's conclusions in paragraph 11 of the NPRM that medical telemetry requires a new spectrum allocation, and that this new spectrum should be allocated on a primary basis for medical telemetry.***

Both the FCC and the Food and Drug Administration ("FDA") recognize the risk to patients regarding disruptive interference to medical telemetry. While no patient injuries have been reported as a result of such interference, there has been an acknowledgment by both the FCC and the FDA that important decisions in the administration of patient care and alarm surveillance could be compromised if critical telemetry patient monitoring is interrupted.

The potential for interference to medical telemetry was clearly demonstrated to both the FCC and FDA in the incident reported at Baylor University Medical Center in March, 1998 involving telemetry equipment of another manufacturer that received interference from the signal of a new digital television ("DTV") station. The FCC has also independently confirmed the potential for interference through testing at its own laboratories.

The current spectrum allocations for medical telemetry require it to tolerate interference from primary users (broadcast television services and private land mobile radio services). Medical telemetry users must seek interference-free bandwidth on an effectively shrinking amount of spectrum, at a time when the demand for more spectrum for telemetry monitoring is increasing. From a public policy standpoint, the needs of medical telemetry fill a greater public policy need than many other competing needs.

Currently, telemetry is forced to provide mission critical data transmission as a secondary user in spectrum allocations that are inadequate for meeting current and future monitoring needs. The evidence on this point already before the Commission is overwhelming:

- the results of interference compatibility testing using simulated transmissions of current and proposed private land mobile radio (PLMR) devices;
- the public evidence of digital television (DTV) interference with medical telemetry in hospital monitoring settings; and
- the documented uses and benefits medical telemetry has produced in public health.

These facts inescapably point to the need for dedicated spectrum that will accommodate the growing requirements for medical telemetry patient monitoring, and to the need for a regulatory status for medical telemetry that will offer it protection and remedy from interference from other spectrum users.

2. ***Spacelabs supports spectrum option 1 (608-614 MHz; 1395-1400 MHz and 1429-1432 MHz) as the preferred frequency allocation for the WMTS.***

The Commission has requested comments in paragraph 21 of the NPRM, on which band, in addition to 608-614 MHz, would be preferred for use by medical telemetry in the 1390 MHz to 1432 MHz. As noted in the AHA Task Force report to the FCC, at least 12 MHz of spectrum will be required over the next ten years to accommodate the anticipated uses of medical telemetry devices. This would imply that at least two 6 MHz blocks of spectrum should be identified for medical telemetry use.

Further, although Spacelabs does support the 608-614 MHz band dedicated for medical telemetry, there are population center locations in which medical facilities seeking to employ telemetry monitoring, will fall within the 80 km (50 miles) radius of a Radio Astronomy Observatory (RAO) or a Very Long Baseline Array (VLBA) site, and for which no practical remedy may exist to avoid interference to these protected primary users in the 608-614 MHz band. The only remedy that will permit medical telemetry operations and protect these users is an alternative frequency band for medical telemetry. Today this situation would be accommodated by continued use of the Part 15 and Part 90 bands. However, another dedicated band, that is not shared with incompatible spectrum partners, must be identified for medical telemetry.

Spacelabs Medical supports the split band option, Option 1, over Option 2 identified by the FCC, which would involve the use of 1395-1400 MHz and 1429-1432 MHz for medical telemetry, in addition to the 608-614 MHz band.

The key benefits of option 1 for medical telemetry include:

- Frequency separation from high powered radar located below 1390 MHz.
- Spectrum bifurcation to more easily support telecommand with bi-directional telemetry operations.
- Early access to 1429-1432 MHz as a result of radar decommissioning in 2004.
- Less potential for adjacent band (1427-1429 MHz) high power interference (Radio Astronomy users).
- Less economic impact to existing spectrum users for decommissioning and relocation.

In sum, Option 1 should be the clearly preferred choice for the WMTS.

3. ***Spacelabs strongly urges the FCC to "grandfather" the use of equipment that is currently authorized under Part 15 and Part 90 of the rules and that is purchased within 2 years after finalization of the instant rulemaking.***

Spacelabs supports the Commission's intent in paragraph 41 of the NPRM that all new medical telemetry equipment authorized from the second anniversary of the adoption of rules for the WMTS operate on the new frequency bands. However, Spacelabs strongly opposes what appears to be a proposal in the

NPRM that after that two year anniversary, equipment that has been purchased through that date by hospitals (and other health care providers) and authorized by the FCC to operate under Part 15 and Part 90 of the rules, will no longer be legally allowed to be used.

The failure to grandfather devices that were lawfully purchased by hospitals at significant cost and expense, could have dramatic and costly implications for health care in the United States. It would render obsolete, by regulatory fiat, valuable medical telemetry devices at a cost to the healthcare system on the order of $100 million. While Spacelabs might be a potential beneficiary of such a rule, since it would reap the benefits of selling significant quantities of new medical telemetry equipment to its customers, Spacelabs does not believe such a rule would be consistent with the public interest and strongly opposes such a rule.

Instead, Spacelabs proposes that any medical telemetry equipment authorized under Part 15 and Part 90 and purchased on or before the two year anniversary of the finalization of the instant rulemaking, be continued to be permitted to be used after such finalization. Continued operation of this equipment would be determined by the degree of potential interference the hospital may experience and the hospital's own equipment depreciation periods (on average, a maximum of 5 to 7 years). The continued servicing and supply of replacement parts for such equipment should also be clarified to be permitted.

4. ***Spacelabs urges FCC not to lift the Refarming freeze in the 460-470 MHz band within 5 years of the date of the finalization of this rulemaking, and suggests that the freeze in the 450-460 MHz band be lifted within 1 year to accommodate competing services.***

The Commission has requested comments in paragraph 42 of the NPRM on the AHA's proposal to lift the freeze on licenses for high power users in the 450-470 MHz Private Land Mobile Radio Service (PLMRS) band 5 years after the adoption of rules allocating spectrum for medical telemetry equipment. Spacelabs recognizes that there are other services that seek access to spectrum in this range. However, as a matter of public record, Spacelabs has opposed lifting this freeze until there is a clear practical plan in place to migrate medical telemetry users to a dedicated spectrum that greatly reduces the potential for disruptive interference. The concept of a "practical" plan clearly requires adequate lead time to transition an industry to new spectrum. Given the replacement purchasing needs of hospitals, as well as the lead time of product develop cycles and the requirement to obtain regulatory agency clearances and approvals (e.g. FCC and FDA) prior to commercial distribution, this transition will be complex under the best of circumstances. The process should not be complicated further by artificial regulatory timelines.

Spacelabs Medical advocates the following practical plan regarding the potential for the lifting of the Refarming Freeze. This plan accommodates both practical reality and the competing needs of other services.

Specifically, Spacelabs believes that the Refarming Freeze may be lifted within 1 year in the 450-460 MHz band. The significant majority of medical telemetry operations are in the 174-216 MHz range and the 460-470 MHz range. To protect users in the 450-460 MHz band, Spacelabs proposes that the Commission provide a transition period equal to one year from the adoption of rules allocating new, dedicated spectrum for medical telemetry equipment.

This proposed transition period provides near-term spectrum access for PLMRS users, without creating disruptive interference for medical telemetry operations in the 460-470 MHz band where the majority of telemetry users lie. In this band, a 5 year transition (the minimum assumed equipment depreciation period) is required. Such a transition period allows for hospitals to plan, budget, and to install equipment in the new WMTS bands, and also permits the registration process to be introduced and developed.

5. ***Spacelabs supports adoption of AHA's spectrum requirements analysis and spectrum efficiency metric assumption.***

Spacelabs believes that the analysis of spectrum requirements conducted by AHA's Task Force on Medical Telemetry is reasonable and thorough. It urges the Commission to use these results as the basis for making an allocation of dedicated spectrum for medical telemetry.

Spacelabs does not believe that the assumed spectral efficiency metric is currently or readily achievable on a broad basis in light of technological restrictions, as well as product development and regulatory approval lifecycles. Spacelabs does believe that the assumed spectral efficiency of 0.8 bits per second per Hertz may be achievable within 2 years of the finalization of the proposed rulemaking. We do not believe, however, that a more stringent spectral efficiency metric would be readily achievable in this timeframe nor do we believe that an acceleration of this 2 year timeframe would be reasonable.

6. ***Medical telemetry is not likely to cause interference to terrestrial Little LEO systems. However, these services may cause interference to medical telemetry, and the FCC needs to ensure that this interference is avoided.***

In paragraph 14 of the NPRM, the Commission requests comments on the possible impact of medical telemetry allocation in the 1385-1435 MHz band and other potential spectrum occupants, including terrestrial mobile systems and Little LEO satellite systems. Spacelabs has determined that, to suffer interference from medical telemetry operations, systems that employ receivers with sensitivities as low as 0.1μvolt would have to be located at least 260 feet from a health care facility that contains a medical telemetry transmitter generating a field strength of 740 mV/meter @ 3 meters.

The following analysis assumes a biomedical telemetry transmitter operating at 1400 MHz, produces a maximum field strength of 740 mV/meter @ 3 meters

(the proposed maximum allowable output for an authorized biomedical telemetry transmitter in this band) on the same frequency used by a terrestrial or Little LEO receiver that has a minimum sensitivity of 0.1μvolt. Further, it is assumed that no interference to these devices by a biomedical telemetry transmitter will occur, if the received co-channel signal falls below the other receiver's minimum sensitivity.

- The power at a LLEO/LMCC receiver antenna to produce at 0.1μV rms potential across 50Ω = $E^2/R = 2 \times 10^{-16}$ W
- To determine what power density is required, the intercept area of λ/2 dipole is computed (from p. 33-21 of the ITT Handbook for Radio Engineers, 7th edition): $A_{\lambda/2} = .13\lambda^2$, where λ = 0.214 meters; $A_{\lambda/2} = .13(.214)^2 = 5.96 \times 10^{-3}$ m^2
- The required power density = $(2 \times 10^{-16}$ W)/(5.96×10^{-3} m^2) = 3.35×10^{-14} W/m^2
- The field strength, $\mathbb{E} = (P_D \times R)^{1/2}$, where R = 377ohm; $\mathbb{E}$ = 3.55 μV/meter
- Power ratio = α = (radiating field strength)/(received field strength) = $(740 \times 10^{-3})/(3.55 \times 10^{-6}) = 2.08 \times 10^5 \Rightarrow$ Path loss = 10 log α = 73.19 dB
- From p. 33-21 of the ITT Handbook, at 1400 MHz, the range is less than 260 feet for a path loss of 73.19 dB.

This analysis is conservative. It assumes no attenuation of the biomedical telemetry signal due to the hospital facility construction and it takes into account various worst-case scenarios: e.g., the patient who may stand in front of an unshielded window, thereby affording no attenuation to the radiated telemetry signal; and the fact that while the antenna gain for a patient-worn medical telemetry device is typically negative, a monitor could be placed on a metal surface, e.g., after removal from a patient, with the power still on, and thereby become a more efficient radiator.

While the separation distance to avoid interference to Little LEO devices may be practical, such a separation distance may not be realistic and enforceable for terrestrial mobile devices. The conclusion that can be drawn from this is that a sharing arrangement in the 1385-1435 MHz band with Little LEO systems may be possible, but it is not with terrestrial mobile systems. The latter situation would represent the incompatibility that exists today in the Part 90 band between low power medical telemetry and full power land mobile services.

Obviously, the potential for interference to medical telemetry from Little LEO uplinks and downlinks, and land mobile devices increases if the band is shared. In response to paragraph 21 of the NPRM, since the power levels of these devices are assumed to be much higher than that of medical telemetry, much greater separation distances would be required to avoid co-channel interference. Thus, care must be taken to ensure that the problems that exist in the existing telemetry bands are not simply transferred to the new ones. Such precautions could not be guaranteed with LLEO downlinks or land mobile devices.

7. ***Spacelabs supports the Commission's proposal on field strength and out-of-band emissions limits.***

Spacelabs supports the Commission's recommendation in paragraph 36 of the NPRM to limit the WMTS field strength in the 608-614 MHz band to 200 mV/m @ 3 meters. This is the identical field strength limit that currently exists for medical telemetry devices authorized under Part 15.242 of the rules, and is lower than the 25mW (370 mV/m @ 3 meters) EIRP limit that is specified in ETSI 300 220, the European standard for low power telemetry.

The free space transmission path loss at 614 MHz is approximately 2.7 dB more than that at 470 MHz. Medical telemetry products marketed in the 460-470 MHz band are operating reliably with typical specified output powers of 2mW to 4mW. ET Docket 95-177 increased the maximum allowable output power by approximately 3dB above this level for medical telemetry devices authorized under Part 15.242 to approximately 7.3 mW (200 mV/m @ 3 meters). It can be reasonably expected that the increased maximum output power (+3dB) will compensate for the increased path loss (- 2.7 dB) at the higher operating frequency to result in equivalent medical telemetry operations.

Another perspective on the proposed field strength limits is to assume the adequacy of 200mV/m @ 3 meters at 470 MHz. As noted above, typical medical telemetry devices operating in the 460-470 MHz range today produce field strengths slightly below this level. A field strength of 200mV/m @ 3 meters at 470 MHz, corresponds to 258 mV/m @ 3 meters at 611 MHz.

In order to reduce operational costs for medical facilities, telemetry manufacturers seek to produce power efficient transmitters that have extended battery service lives. The 200 mV/m field strength level provides an acceptable trade-off between recurring costs (battery replacement) and fixed costs (antenna system), while also reducing the potential of undesirable interference to other spectrum occupants (e.g., Radio Astronomy Observatories).

The field strength limits proposed by FCC in the 608-614 MHz band (200 mV/m @ 3 meters) and in the 1385-1435 MHz band (740 mV/m @ 3 meters) are reasonable limits to balance reliable and effective reception with avoidance of interference to other devices or users.

The out-of-band emissions limit (200μV/m @ 3 meters) for 608-614 MHz outlined in paragraph 37 of the NPRM is identical to that currently specified under Part 15.242. In its petition to FCC as part of ET Docket 95-177, the Critical Care Telemetry Group (CCTG) demonstrated in its Engineering Statement that these out-of-band emissions limits would prevent interference to adjacent television channels (in this case, broadcast television channels 36 and 38). This out-of-band limit is more stringent than that for Part 90 medical telemetry devices. As noted in the NPRM, FCC has been successful in using

this 200μV/m limit to control interference. Spacelabs Medical supports this out-of-band emissions limit.

8. ***Spacelabs Medical supports the eligibility requirement for the WMTS outlined in paragraph 28 of the NPRM but urges that this eligibility be extended to include in-home patient monitoring.***

Health care today is in a dynamic transition. We have seen marked emphasis placed by the federal government and private policy makers on reducing length of stay in acute care facilities and shifting such care to sub-acute facilities, skilled nursing facilities, and home care. This shift has significantly improved outcomes, quality of life, and reduced costs to the health care system. Moreover, with the advent and integration of the Internet into our daily lives, it becomes more and more foreseeable that home care telemetry monitoring will be both technically feasible and a practical alternative in the near future.

The FCC's rulemaking should support these public health objectives by permitting future consideration of in-home patient monitoring with the eligibility requirement for the WMTS. Absolute prohibition of home care telemetry monitoring will stifle needed innovation to address reduction in health care costs. It is clear that even on a case-by-case basis, such issues as physician oversight and spectrum coordination can be addressed through the proposed coordination process. The proposed bands of the WMTS will avoid interference to existing broadcast users and will not be subject to the potential of interference from unlicensed devices.

CONCLUSION

As the result of the foregoing, Spacelabs requests that the Commission expeditiously adopt the rules proposed in the NPRM, consistent with the modifications set out herein.

Respectfully submitted,

SPACELABS MEDICAL, INC.

By: Eugene V. DeFelice

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Secretary

September 10, 1999

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